

Claim Rejections Under 35 USC §103

Claim 18 is directed to a bi-directional hinge capable of rotation forwards and backwards of a center position. When applied to the joint of a patient, such as a knee, this means that the hinge can allow the knee joint to rotate forward into an abnormal position. In an injured or postoperative patient the joint structure may be damaged and unable to prevent such abnormal rotation, so that a hinge is applied to prevent this from happening. Previous hinges such as mentioned in this applicant's specification as prior art are not bi-directional, and accidental disengagement of the detent presents a lesser risk. Such safeguard is particularly important in the hinge of Claim 18 which is capable of rotation above and below a zero center position. In the claimed bi-directional hinge a higher level of safety is appropriate without sacrifice in convenience to the therapist who must install, remove or adjust the hinge. The invention as now claimed in Claim 18 offers a solution by providing a tamper resistant yet easy to operate detent in a bi-directional hinge. Claim 18 has been amended by new language reciting the detent element being protected against disengagement by an unaided hand. This tamper-resistant construction minimizes or avoids the possibility that a patient may intentionally or accidentally disengage the detent of the hinge and thereby cause him or herself serious injury. In a bi-directional splint hinge such as disclosed and claimed by this applicant, the risk of wrong way rotation of the patient's joint is substantially diminished or eliminated by provision of the tamper-deterrent feature which has now been incorporated into Claim 18.

The *Johnson* reference, which the Examiner cites as showing bi-directional rotation on either side of a straight, center position, is not designed or intended to fix the joint at a particular angle. Rather, it is only designed to set a permissible range of angular rotation for the joint. The limits of angular rotation are set by disks fastened by a set screw through the center of the various disks shown in Figure 1 of that reference.

Applicant's hinge of Claim 18 is designed to lock the joint at a particular angle. The tamper-resistant detent of applicant's hinge prevents its release by a patient and thereby minimizes the risk of serious injury to the patient through tampering or accidental manipulation and release of the detent. Specifically, this applicant is the first to provide a tamper-resistant detent of simple design which is spring-urged into locking condition and can be readily retracted

and disengaged against the spring-urging. Claim 18, as now amended, is believed to patentably distinguish over the cited art.

Claims 19 and 20, being dependent on Claim 18, incorporate patentable subject matter and are allowable with the patent claim.

Claim 21 has been indicated to be allowable if combined with parent Claim 18. The present amendment to Claim 18, in effect, accomplishes this to a large extent, although in a somewhat broader fashion than incorporation of Claim 21 into Claim 18.

Claim 26 has been rejected in view of the admitted prior art and *Bloedau*. Responsive to the rejection, Claim 26 has been amended in a manner similar to that of Claim 18, by incorporation therein of a tamper-deterrant means arranged for protecting the detent element against displacement out of engagement by an unaided hand. It is urged that, as so amended, Claim 26 is allowable for reasons analogous to those explained in connection with Claim 18.

New dependent Claims 27 and 28 recite novel features relating to visual directional markings on the wheels of the hinge and radially extending tabs bearing those directional markings in combination with the hinge of Claim 26. Provision of these directional markings in Claim 27 greatly facilitate adjustment of the hinge in that they readily identify the direction of rotation of the wheels to the therapist. Provision of the radially extending tabs in Claim 28 facilitates manipulation and adjustment of the wheels in conjunction with the directional markings. The features recited in Claims 27 and 28 are novel over the prior art and these claims are believed allowable with their parent Claim 26.

New independent Claim 29 is a combination of the elements recited in Claim 26 and the directional markings of new dependent Claim 27. The prior art relied upon by the Examiner shows no hinge structure with the directional markings on the two wheels which define the range of motion of the hinge. Claim 30, dependent on new Claim 29, specifies that the directional markings are on tabs extending radially from the two wheels.

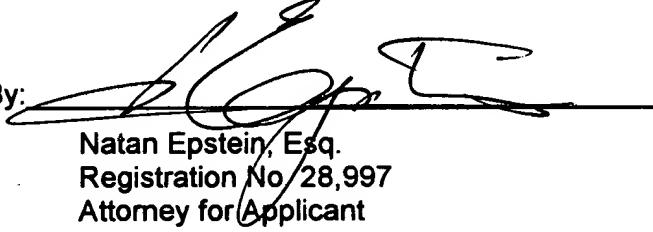
New dependent Claims 31 and 32 add the tamper-deterrent feature to the hinge of Claim 29. The tamper-deterrent protection has been discussed above in this response and is novel over the art of record, particularly in combination with the features set forth in new Claim 29.

Review and reconsideration of the application, as now amended, is respectfully requested. All claims now pending are believed to be in condition for immediate allowance and such action is earnestly solicited. The undersigned is available for telephone discussion of any aspect of this application in the interest of expediting prosecution of this case.

Respectfully submitted,

Dated: October 22, 2002

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Response to Office Action dated 06/12/2002
MARKED UP COPY OF THE AMENDED CLAIMS

5 1 (once amended). A hinge for an orthopedic splint comprising:
an upper plate and a lower plate connected for pivotal movement, a detent
[element] supported on said upper plate and displaceable into and out of an
engaged condition thereby to lock the two plates against said pivotal movement
in a selected angular relationship relative to each other, a spring normally urging
10 said detent into said engagement, cover means protecting said detent [element]
against displacement out of said engagement by an unaided hand, and an
aperture in said cover means sized and disposed for admitting a tool end
operative for displacing said detent out of said engagement against said urging of
said spring and thus to free the plates for said pivotal movement, whereby
15 tampering with the angular setting of said hinge by a patient wearing said
orthopedic splint is discouraged.

2. The hinge of Claim 1 wherein said detent is displaceable in a guide way
defined between said upper plate and said cover means.

20 3. The hinge of Claim 2 wherein said spring is contained in said guide way.

4 (once amended). The hinge of Claim 3 wherein said spring is a coil spring
compressed between said upper plate [spacer] and said detent.

25 5. The hinge of Claim 1 wherein said detent is engageable with a toothed edge
on said lower plate.

6. The hinge of Claim 1 wherein said aperture is a slot aligned with a direction of displacement of said detent, said slot being sized and dimensioned to allow visual confirmation of engagement of said detent with said toothed edge.

5 7. The hinge of Claim 1 wherein said detent has a tool end receptacle adapted to receive the said tool end thereby to facilitate displacement of said detent by means of a said tool end.

10 8. The hinge of Claim 1 wherein said pivotal movement comprises an arc including a zero angle position at an intermediate location along said arc, such that said plates may be moved through substantial angular ranges on either side of said zero angle position.

15 9. The hinge of Claim 8 wherein said zero angle position is centered along said arc such that said plates may be pivoted through equal angular ranges on either side of said zero angle position.

10. The hinge of Claim 9 wherein said plates are aligned in a straight line in said zero angle position.

20 11. The hinge of Claim 1 further comprising a locking element removably engageable with said detent for holding said detent out of said engagement thereby to facilitate adjustment of the plates to a desired angular relationship.

25 12. The hinge of Claim 11 wherein said locking element is threaded for engagement with said detent.

13. The hinge of Claim 12 wherein said locking element is a screw engageable in a threaded screw hole defined in said detent, such that an end of said screw

bears against said upper plate or engages with a hole in the upper plate thereby to hold said detent against said urging of said spring.

14. The hinge of Claim 1 further comprising range setting means engageable by
5 said detent, said range setting means being adjustable for limiting said pivotal
movement to a greater or lesser arc in a disengaged condition of said detent.

15. The hinge of Claim 14 wherein said range setting means comprises a pair of
wheels turning concentrically with said pivotal movement of the plates, each of
10 said wheels having a wheel edge engageable by said detent for locking the
wheel relative to said upper plate, and a stop on each of said wheels operative
for limiting pivotal movement of said lower plate relative to said upper plate in
one direction of movement, a stop pin on said lower plate being disposed
between the two stops such that the range of pivotal movement between the
15 plates may be set by the angular spacing between the two stops when said
detent is engaged for locking said wheels against rotation relative to said upper
plate.

16 (once amended). The hinge of Claim 1 further comprising tabs projecting
20 radially from said wheel edge of said wheels and directional markings on said
tabs [in said tabs] as a visual indicator for assisting a therapist in determining the
relative positions of the tabs during adjustment of the hinge.

17 (once amended). The hinge of Claim 1 wherein said cover means includes a
25 spacer mounted to said upper plate and defining a guide way for said detent and
a cover plate for containing said detent in said guide way.

18 (once amended). A hinge for an orthopedic splint comprising:
an upper plate and a lower plate connected for pivotal movement, a detent
30 element supported on said upper plate and displaceable into and out of an

engaged condition thereby to lock the two plates against said pivotal movement in a selected angular relationship relative to each other, a spring normally urging said detent into said engagement, wherein said pivotal movement comprises an arc including a zero angle position at an intermediate location along said arc,

5 such that said plates may be moved through substantial angular ranges on either side of said zero angle position, and tamper deterrent means arranged for protecting said detent element against displacement out of said engagement by an unaided hand.

10 19. The hinge of Claim 18 wherein said zero angle position is centered along said arc such that said plates may be pivoted through equal angular ranges on either side of said zero angle position.

15 20. The hinge of Claim 19 wherein said plates are aligned in a straight line in said zero angle position.

21 (once amended). The hinge of Claim 18 wherein said tamper deterrent means comprise [further comprising] cover means protecting said detent element against displacement out of said engagement by an unaided hand, and an aperture in said cover means sized and disposed for admitting a tool end operative for displacing said detent out of said engagement against said urging of said spring and thus to free the plates for said pivotal movement, whereby tampering with the angular setting of said hinge by a patient wearing said orthopedic splint is discouraged.

25 22 (once amended). A hinge for an orthopedic splint comprising:
an upper plate and a lower plate connected for pivotal movement, a detent [element] supported on said upper plate and displaceable into and out of an engaged condition thereby to lock the two plates against said pivotal movement
30 in a selected angular relationship relative to each other, a spring normally urging

said detent into said engagement, and a locking element removably engageable with said detent for holding said detent out of said engagement thereby to facilitate adjustment of the plates to a desired angular relationship.

- 5 23. The hinge of Claim 22 wherein said locking element is threaded for engagement with said detent.
- 10 24. The hinge of Claim 23 wherein said locking element is a screw engageable in a threaded screw hole defined in said detent, such that said screw engages said upper plate thereby to hold said detent in a disengaged condition against said urging of said spring.
- 15 25. The hinge of Claim 24 wherein said screw is removable from the splint thereby to discourage tampering with the detent or may be left in place and tightened to secure said detent in said engaged condition.
- 20 26 (once amended). A hinge for an orthopedic splint comprising: an upper plate and a lower plate connected for pivotal movement, a detent element supported on said upper plate and displaceable into and out of an engaged condition thereby to lock the two plates against said pivotal movement in a selected angular relationship relative to each other, a spring normally urging said detent into said engagement, a pair of wheels turning concentrically with said pivotal movement of the plates, each of said wheels having a wheel edge engageable by said detent for locking the wheel relative to said upper plate, and
- 25 a stop on each of said wheels operative for limiting pivotal movement of said lower plate relative to said upper plate in one direction of movement, [said] a pin on said lower plate [being] disposed for movement between the two stops such that the range of pivotal movement between the plates may be set by the angular spacing between the two stops when said detent is engaged for locking said
- 30 wheels against rotation relative to said upper plate, and tamper deterrent means

arranged for protecting said detent element against displacement out of said engagement by an unaided hand.

27 (new). The hinge of Claim 26 further comprising directional markings on said 5 wheels as a visual indicator for assisting a therapist in setting the relative angular positions of the wheels during adjustment of the hinge.

28 (new). The hinge of Claim 27 wherein said directional markings are on tabs extending radially from said wheels.

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29 (new). A hinge for an orthopedic splint comprising:

an upper plate and a lower plate connected for pivotal movement, a detent element supported on said upper plate and displaceable into and out of an engaged condition thereby to lock the two plates against said pivotal movement 15 in a selected angular relationship relative to each other, a spring normally urging said detent into said engagement, a pair of wheels turning concentrically with said pivotal movement of the plates, each of said wheels having a wheel edge engageable by said detent for locking the wheel relative to said upper plate, and a stop on each of said wheels operative for limiting pivotal movement of said 20 lower plate relative to said upper plate in one direction of movement, said pin on lower plate being disposed between the two stops such that the range of pivotal movement between the plates may be set by the angular spacing between the two stops when said detent is engaged for locking said wheels against rotation relative to said upper plate, and directional markings on said wheels provided as 25 a visual indicator for assisting a therapist in setting the relative angular positions of the wheels during adjustment of the hinge.

30 (new). The hinge of Claim 29 wherein said directional markings are on tabs extending radially from said wheels.

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31 (new). The hinge of Claim 29 further comprising tamper deterrent means arranged for protecting said detent element against displacement out of said engagement by an unaided hand.

5 32 (new). The hinge of Claim 31 wherein said tamper deterrent means comprise a cover protecting said detent element against displacement out of said engagement by an unaided hand, and an aperture in said cover sized and disposed for admitting a tool end operative for displacing said detent out of said engagement against said urging of said spring and thus to free the plates for said
10 pivotal movement, whereby tampering with the angular setting of said hinge by a patient wearing said orthopedic splint is discouraged.